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GENENTECH, INC., and CITY OF HOPE

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

GLAXO GROUP LIMITED and GLAXOSMITHKLINE LLC, Plaintiffs, v. GENENTECH, INC., and CITY OF HOPE, Defendants.	Case No. 3:10-cv-00675-JSW **ANSWER AND COUNTERCLAIM TO THE COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY, UNENFORCEABILITY, AND NONINFRINGEMENT**

Genentech, Inc. ("Genentech") and City of Hope ("COH") file this answer in response to the Complaint for Declaratory Judgment of Invalidity, Unenforceability, and Noninfringement (hereinafter "Complaint") of Glaxo Group Limited and Glaxosmithkline, LLC (collectively, "GSK").

NATURE OF THE CASE

1. Genentech and COH admit that GSK purports to seek a declaration in this action relating to U.S. Patent No. 6,331,415 ("the Cabilly II patent"), including *Ex Parte* Reexamination Certificate No. 6,331,415 C1 ("Cabilly Reexam Certificate"), which issued May 19, 2009 pursuant to Reexamination Nos. 90/007,542 and 90/007,859. Otherwise, Genentech and COH deny the allegations in Paragraph 1 of the Complaint.

2. Genentech and COH admit, upon information and belief, that "GSK recently began marketing and selling Arzerra™ in the United States for the treatment of patients whose chronic lymphocytic leukemia ("CLL") is refractory to previous therapies (fludarabine and alemtuzumab)." Genentech and COH deny the remaining allegations in Paragraph 2 of the Complaint.

3. Genentech and COH only admit that "Genentech, Inc. has specifically identified GSK's Arzerra™ antibody product as a potential competitor to one of Genentech's own products" as alleged in Paragraph 3 to the extent that Genentech stated in its Form 10-K for 2008, filed February 19, 2009, that "Rituxan may face future competition in both hematology-oncology and RA from Arzerra™ (ofatumumab), an anti-CD20 antibody being co-developed by Genmab A/S and GSK." Otherwise, Genentech and COH deny the allegations in Paragraph 3 of the Complaint.

THE PARTIES

4. Genentech and COH admit that Glaxo Group Limited does business as GlaxoSmithKline and purports to be an English corporation having a principal place of business at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 ONN, United Kingdom. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4 of the Complaint and accordingly these allegations are denied.

5. Genentech and COH admit that GlaxoSmithKline LLC appears on the publicly available website of the Department of State for the State of Delaware as a Delaware limited liability corporation

incorporated October 27, 2009 and purports to be a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 of the Complaint and accordingly these allegations are denied.

6. Genentech and COH admit the allegations in Paragraph 6 of the Complaint.

7. Genentech and COH admit the allegations in Paragraph 7 of the Complaint.

8. Genentech and COH admit the allegations in Paragraph 8 of the Complaint.

JURISDICTION AND VENUE

9. Genentech and COH admit that Plaintiffs purport to have brought this action under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201 – 2201 (sic)), Title 28 of the United States Code, and the patent laws of the United States, Title 35 of the United States Code. Otherwise, Genentech and COH deny the allegations in Paragraph 9 of the Complaint.

10. Genentech and COH admit that this Court has personal jurisdiction over Genentech and COH for the purposes of this action. Otherwise, Genentech and COH deny the allegations in Paragraph 10 of the Complaint.

11. Genentech and COH admit that venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b) because Genentech and COH admit that this Court had personal jurisdiction over Genentech and COH for the purposes of this action at the time this action was commenced. Genentech and COH contend that, for the convenience of the parties and witnesses, in the interest of justice, this action should be transferred to the Central District of California pursuant to 28 U.S.C. § 1404(a). Otherwise, Genentech and COH deny the allegations in Paragraph 11 of the Complaint.

INTRADISTRICT ASSIGNMENT

12. Genentech and COH admit that intradistrict assignment in the San Francisco Division is appropriate in this action. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 12 of the Complaint and accordingly these allegations are denied.

THE CABILLY PATENTS

13. Genentech and COH admit the allegations in Paragraph 13 of the Complaint.

14. Genentech and COH admit only that, at the time that U.S. Patent No. 4,816,567 ("the Cabilly I patent") issued, the Cabilly I applicants had a continuation application ("the Cabilly II application") pending in the United States Patent and Trademark Office ("PTO"). Genentech and COH also admit that, per standard PTO practice, claims were copied from U.S. Patent No. 4,816,397 (the "Boss patent") into the Cabilly II application in order to provoke the PTO to initiate an interference proceeding. Otherwise, Genentech and COH deny the allegations in Paragraph 14 of the Complaint.

15. Genentech and COH admit that, on February 28, 1991, the PTO declared a patent interference, Interference No. 102,572, between certain claims pending in the Cabilly II application corresponding to the interference counts and all of the issued claims of the Boss patent. Genentech and COH further admit that the text quoted in the allegations of Paragraph 15, without any added emphasis, appears in the document *Cabilly v. Boss*, 55 U.S.P.Q.2d 1238 (B.P.A.I. Aug. 13, 1998), a document that speaks for itself. Otherwise, Genentech and COH deny the allegations in Paragraph 15 of the Complaint.

16. Genentech and COH admit that in October 1998 Genentech filed against Celltech Therapeutics Ltd. ("Celltech"), pursuant to 35 U.S.C. § 146, Civil Action No. 98-3926 in this District ("the 146 Action") and that, on March 6, 2001, the parties to the 146 Action filed a document titled "Notice of Settlement and Joint Request for Entry of Settlement Instruments," (D.I. 104 in the 146 Action). Genentech and COH further admit that the precise terms of the Genentech-Celltech settlement agreement are confidential. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth as to whether "[t]he precise terms of the [Genentech-Celltech] settlement agreement are . . . despite reasonable inquiry, unknown to GSK" and accordingly this allegations is denied. Genentech and COH deny the remaining allegations in Paragraph 16 of the Complaint.

17. Genentech and COH deny the allegations in Paragraph 17 of the Complaint.

18. Genentech and COH admit that the Court in the 146 Action issued a "Judgment" order on March 16, 2001 that speaks for itself. Genentech and COH further admit that "[t]he Cabilly II patent issued on December 18, 2001, and on its face is assigned to Genentech, and, by certificate of correction, is also assigned to City of Hope." Otherwise, Genentech and COH deny the allegations in Paragraph 18 of the Complaint.

19. Genentech and COH deny the allegations in Paragraph 19 of the Complaint.

20. Genentech and COH admit only that Genentech's Form 10-K for 2008, filed February 19, 2009, reports "Royalty Revenue" contributions related to the Cabilly II patent of $298 million for 2008. Genentech and COH deny the remaining allegations in Paragraph 20 of the Complaint.

21. Genentech and COH admit that two requests to reexamine the Cabilly II patent were submitted to the PTO in 2005, that the PTO mailed two separate orders granting a request for reexamination, on July 7, 2005 and January 23, 2006, respectively, and that these reexamination proceedings were merged on June 6, 2006. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 21 of the Complaint and accordingly these allegations are denied.

22. Genentech and COH admit only that, during the reexamination of the Cabilly II patent, the PTO mailed an Advisory Action on July 19, 2008, a document that speaks for itself. Genentech and COH deny the remaining allegations in Paragraph 22 of the Complaint.

23. Genentech and COH admit only that they "filed an Appeal Brief on December 9, 2008" during the reexamination of the Cabilly II patent. Otherwise, Genentech and COH deny the allegations in Paragraph 23 of the Complaint.

24. Genentech and COH admit only that "Genentech amended claims 21, 27, and 32" during the reexamination of the Cabilly II patent. Genentech and COH deny the remaining allegations in Paragraph 24 of the Complaint.

25. Genentech and COH admit the allegations in Paragraph 25 of the Complaint.

26. Genentech and COH admit that the quoted text in Paragraph 26, Subparagraphs a.-k., of the Complaint appears substantially as quoted in an Appeal Brief dated December 9, 2008 and that this Appeal Brief speaks for itself. Genentech and COH deny the remaining allegations in Paragraph 26 of the Complaint.

GSK'S OFATUMUMAB (ARZERRA™)

27. Genentech and COH admit only, on information and belief, that GSK is marketing a human monoclonal antibody, ofatumumab, under the product name Arzerra™, which purportedly aims to target CD20, a naturally occurring protein present on B-lymphocytes. Genentech and COH lack

knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 27 of the Complaint and accordingly these allegations are denied.

28. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 of the Complaint and accordingly these allegations are denied.

29. Genentech and COH admit, on information and belief, that Lonza Biologics plc currently manufactures ofatumumab in the United Kingdom for commercial sale by GSK in the United States as the Arzerra™ product. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 29 of the Complaint and accordingly these allegations are denied.

30. Genentech and COH admit that on October 26, 2009, the United States Food and Drug Administration ("FDA") issued License No. 1809, authorizing GSK to market Arzerra™ with an indication for the treatment of chronic lymphocytic leukemia refractory to fludarabine and alemtuzumab. Genentech and COH further admit, upon information and belief, that GSK has begun marketing, offering for sale, and selling Arzerra™ in the United States. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 30 of the Complaint and accordingly these allegations are denied.

GSK'S DISPUTE WITH GENENTECH REGARDING CABILLY II PATENT

31. Genentech and COH admit that the quoted text in Paragraph 31 of the Complaint, without added emphasis, was attributed in 2002 in the cited *Nature Biotechnology* article to Sean Johnston, then Genentech's Vice President of Intellectual Property and now Genentech's Senior Vice President and General Counsel. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 31 of the Complaint and accordingly these allegations are denied.

32. Genentech and COH admit that the quoted text in Paragraph 32 of the Complaint is from the cited document. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 32 of the Complaint and accordingly these allegations are denied.

33. Genentech and COH admit only that they have asserted the Cabilly II patent in a

counterclaim in response to a complaint filed against them by Centocor. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33 of the Complaint and accordingly these allegations are denied.

34. Genentech and COH admit that Genentech alleges in this pleading that certain activities related to Arzerra™ infringe one or more of the claims of the Cabilly II patent. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33 of the Complaint and accordingly these allegations are denied.

35. Genentech and COH admit, on information and belief, that "both GSK's Arzerra™ and MedImmune's Synagis® are produced by genetically engineering mammalian host cells to produce" an antibody "in cell culture." Genentech and COH further admit, on information and belief, that "Arzerra™ is produced in a recombinant murine (mouse) cell line called NS0." Genentech and COH further admit, on information and belief, that "[o]n information and belief, Synagis® is also produced in a recombinant murine (mouse) cell line called NS0." Genentech and COH further admit, on information and belief, that "Arzerra™ is an IgG1κ monoclonal antibody comprised of two heavy chains and two light chains." Genentech and COH further admit, on information and belief, that "[o]n information and belief, Synagis® is also an IgG1κ monoclonal antibody comprised of two heavy chains and two light chains." Genentech and COH further admit that Genentech alleges in this pleading that certain activities related to Arzerra™ infringe one or more of the claims of the Cabilly II patent. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 35 of the Complaint and accordingly these allegations are denied.

36. Genentech and COH admit that Genentech has alleged that the recombinant methods and starting materials used to produce its Rituxan® antibody product fall within the scope of the Cabilly II patent. Genentech and COH admit, on information and belief, that "[l]ike Arzerra™, Genentech's Rituxan® is produced by genetically engineering mammalian host cells to produce" an "antibody in cell culture." Genentech and COH admit, on information and belief, that "[l]ike Arzerra™, Genentech's Rituxan® is an IgG1κ monoclonal antibody comprised of two heavy chains and two light chains." Genentech and COH admit, on information and belief, that "[l]ike Arzerra™, Genentech's Rituxan® is directed against the CD20 antigen." Genentech and COH admit, on information and belief, that "Lonza

has manufactured Rituxan® for Genentech." Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 36 of the Complaint and accordingly these allegations are denied.

37. Genentech and COH deny the allegations in Paragraph 37 of the Complaint.

38. Genentech and COH deny the allegations in Paragraph 38 of the Complaint.

39. Genentech and COH admit that the quoted text in Paragraph 39 of the Complaint, without added emphasis, appears in (other than the typographical error substituting "license" for "licensee") Genentech's Form 10-K filing for 2008, filed February 19, 2009. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 39 of the Complaint and accordingly these allegations are denied.

40. Genentech and COH admit that the quoted text in Paragraph 40 of the Complaint, without added emphasis, appears in Genentech's Form 10-K filing for 2008, filed February 19, 2009. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 40 of the Complaint and accordingly these allegations are denied.

41. Genentech and COH deny the allegations in Paragraph 41 of the Complaint.

42. Genentech and COH admit only that Genentech and GSK have had discussions and interactions relating to the Cabilly family of patents. Genentech and COH deny the remaining allegations in the introductory sentence of Paragraph 42 of the Complaint. Except as expressly admitted below, Genentech and COH deny the remaining allegations in Paragraph 42 of the Complaint.

a. Genentech and COH, on information and belief, admit the allegations in Subparagraph 42.a. of the Complaint.

b. Genentech and COH deny the allegations in Subparagraph 42.b. of the Complaint, which are improper allegations.

c. Genentech and COH, on information and belief, admit that in 2005 representatives of Genentech and GSK discussed a possible license under the Cabilly II patent for antibodies targeting IL-5. Genentech and COH deny the remaining allegations in Subparagraph 42.c. of the Complaint.

d. Genentech and COH, on information and belief, admit that "[i]n 2005 a

representative of Genentech, Tim Schwartz, asked GSK's counsel, Frank Grassler, to begin a discussion regarding a 'Cabilly license for BEXXAR (anti-CD20) now that GSK has acquired the rights to this product.'" Genentech and COH, on information and belief, further admit that both Arzerra™ and BEXXAR purportedly aim to target the antigen CD20. Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Subparagraph 42.d. of the Complaint and accordingly these allegations are denied.

e. Genentech and COH admit that Mark Lemley is currently outside counsel for Genentech and COH in this matter. Genentech and COH deny the remaining allegations in Subparagraph 42.e. of the Complaint.

43. Genentech and COH deny the allegations in Paragraph 43 of the Complaint.

44. Genentech and COH admit that Genentech and GSK's predecessors-in-interest were previously involved in patent litigations against one another in the 1990s and early 2000s, including at least one relating to recombinant antibodies. Genentech and COH deny the remaining allegations in Paragraph 44 of the Complaint.

PRIOR ACTION IN THE SOUTHERN DISTRICT OF FLORIDA

45. Genentech and COH admit that on October 8, 2009 GSK filed Civil Action No. 09-61608 in the Southern District of Florida ("the Florida Action") seeking a declaratory judgment against Genentech and COH and that Genentech and COH moved to dismiss the Florida Action for lack of subject matter jurisdiction or, in the alternative, to transfer the action to the Central District of California. Genentech and COH also admit that the text quoted in Paragraph 45 of the Complaint appears in Genentech's and COH's motion papers in connection with their motion to dismiss the Florida Action. Genentech and COH further admit that no paper filed in the Florida Action stated that Genentech and COH "would not assert the Cabilly II patent against GSK's Arzerra™ product." Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 45 of the Complaint and accordingly these allegations are denied.

46. Genentech and COH admit the allegations in Paragraph 46 of the Complaint, except to

note that Genentech and COH asserted in the Florida Action that venue was convenient in the United States District Court for the Central District of California. Genentech and COH deny that they suggested venue was convenient in this Court or District. Genentech and COH contend that GSK's dismissal of the Florida action and GSK's filing of the Complaint in this Court constitute forum shopping.

47. Genentech and COH admit that "Genentech [n]ever indicate[d] that a license [to the Cabilly II patent] was unnecessary or that it did not intend to enforce the Cabilly II patent against GSK." Genentech and COH deny the remaining allegations in Paragraph 47 of the Complaint.

48. Genentech and COH admit the allegations in Paragraph 48 of the Complaint.

49. Genentech and COH admit, on information and belief, that the FDA has now approved Arzerra™ for commercial sale only in accordance with License No. 1809 and that GSK has begun selling Arzerra™ in the United States. Genentech and COH further admit that GSK filed this suit in the Northern District of California and that, in this District, Genentech has its headquarters and COH has an established place of business. Genentech and COH deny that "GSK has attempted to discuss the Cabilly II patent with Genentech in the context of Arzerra™, but Genentech declined to respond." Genentech and COH lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 49 of the Complaint and accordingly these allegations are denied.

50. Genentech and COH deny that, at the time GSK filed their Complaint, "[b]ased on all of the circumstances, there [was] an actual and justiciable controversy between GSK and Defendants with respect to whether the manufacture, importation, offer to sell, sale, or use of ofatumumab (Arzerra™) in the United States infringes any valid and enforceable claim of the Cabilly II patent." Accordingly, Genentech and COH deny the allegations in Paragraph 50 of the Complaint.

FIRST CAUSE OF ACTION
(Patent Invalidity)

51. Genentech and COH incorporate by reference their answers to the allegations of paragraphs 1 through 50 as if fully set forth herein.

52. Genentech and COH deny the allegations in Paragraph 52 of the Complaint.

53. Genentech and COH deny the allegations in Paragraph 53 of the Complaint.

54. Genentech and COH deny the allegations in Paragraph 54 of the Complaint.

55. Genentech and COH deny the allegations in Paragraph 55 of the Complaint.

56. Genentech and COH deny the allegations in Paragraph 56 of the Complaint.

57. Genentech and COH admit that GSK seeks the relief described in Paragraph 57 of the Complaint.

SECOND CAUSE OF ACTION
(Non-Infringement)

58. Genentech and COH incorporate by reference their answers to the allegations of paragraphs 1 through 57 as if fully set forth herein.

59. Genentech and COH deny the allegations in Paragraph 59 of the Complaint.

60. Genentech and COH admit that GSK seeks the relief described in Paragraph 60 of the Complaint.

THIRD CAUSE OF ACTION
(Prosecution Laches)

61. Genentech and COH incorporate by reference their answers to the allegations of paragraphs 1 through 60 as if fully set forth herein.

62. Genentech and COH deny the allegations in Paragraph 62 of the Complaint.

63. Genentech and COH deny the allegations in Paragraph 63 of the Complaint.

64. Genentech and COH admit that GSK seeks the relief described in Paragraph 64 of the Complaint.

PRAYER FOR RELIEF

Genentech and COH deny that Plaintiffs are entitled to the relief requested or any other relief.

GENENTECH'S AND COH'S ADDITIONAL DEFENSES

FIRST ADDITIONAL DEFENSE
(Failure To State A Claim)

65. GSK's claims are barred, in whole or in part, as GSK have failed to state a claim upon which relief can be granted.

/ / /

SECOND ADDITIONAL DEFENSE
(Lack of Causation)

66. GSK's Third Cause of Action (prosecution laches) is barred to the extent that Plaintiffs' purported injuries and damages were not proximately caused by acts or omissions of Genentech or COH. There is no causal relationship between the injuries and losses alleged, if any, and any alleged wrongful acts or omissions by Genentech or COH.

RIGHT TO ASSERT ADDITIONAL DEFENSES

67. Genentech and COH expressly reserve the right to assert and pursue additional defenses.

DEMAND FOR JURY TRIAL ON DEFENSES

68. Genentech and COH demand trial by jury on all defenses and issues triable by jury.

COUNTERCLAIM

For their counterclaim against Counter-Defendants Glaxo Group Limited and GlaxoSmithKline LLC, Counter-Plaintiffs Genentech, Inc. and City of Hope allege as follows:

PARTIES

69. Counter-Plaintiff Genentech, Inc. is a corporation organized under the laws of Delaware, with its principal place of business in South San Francisco, California. Genentech is registered to do business and is doing business inside California.

70. Counter-Plaintiff City of Hope is a California not-for-profit organization with its principal place of business in Duarte, California.

71. Counter-Defendant Glaxo Group Limited does business as GlaxoSmithKline, and, on information and belief, is an English corporation having a principle place of business at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 ONN, United Kingdom.

72. Counter-Defendant GlaxoSmithKline LLC, on information and belief, is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102.

JURISDICTION AND VENUE

73. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq*., and jurisdiction is therefore properly based on Title 35 of the United States Code, § 271, and Title

28 of the United States Code, § 1338(a).

74. This Court has personal jurisdiction over Glaxo Group Limited by virtue of, *inter alia*, its having conducted business inside the State of California, having subjected itself to the jurisdiction of this Court by filing this action, having availed itself of the rights and benefits of California law, and having systematic and continuous contacts with the State of California.

75. This Court has personal jurisdiction over GlaxoSmithKline LLC by virtue of, *inter alia*, its having conducted business inside the State of California, having subjected itself to the jurisdiction of this Court by filing this action in the District, having availed itself of the rights and benefits of California law, and, on information and belief, having systematic and continuous contacts with the State of California.

76. Counter-Defendants are actively recruiting new hires in California. *See* http://us.gsk.com/html/career/jobsearch.html (last visited March 4, 2010) (advertising one or more open positions for Counter-Defendants in California for "experienced hires").

77. Counter-Defendants also subjected themselves voluntarily to the personal jurisdiction of this Court and this District by filing this action.

78. On information and belief, GSK continuously and systematically market and sell their products in the State and in this District.

79. Venue is proper in this District pursuant to Title 28, United States Code, §§ 1391(c) and 1400(b).

THE CABILLY II PATENT

80. On December 18, 2001, the Cabilly II patent was issued by the PTO, and on May 19, 2009, the Cabilly Reexam Certificate was issued by the PTO. (A true and correct copy of U.S. Patent No. 6,331,415, the Cabilly II patent, is attached as Exhibit A, and a true and correct copy of the Cabilly Reexam Certificate, *Ex Parte* Reexamination Certificate No. 6,331,415 C1, is attached as Exhibit B). Reexamination of the Cabilly II patent in the PTO, as shown on the Cabilly Reexam Certificate, confirmed the patentability of claims 1-20 and 33-36. The amended claims of the Cabilly Reexam Certificate are incorporated into the Cabilly II patent by operation of 35 U.S.C. § 307 and applicable law.

81. Genentech and COH are the co-owners by assignment of the right, title, and interest in the Cabilly II patent.

82. On information and belief, GSK have known of the Cabilly II patent since at least 2002.

COUNTER-DEFENDANTS' OFATUMUMAB, A/K/A ARZERRA™

83. Counter-Defendants have stated—and Counter-Plaintiffs allege—that Counter-Defendants have begun marketing and selling a human monoclonal antibody, ofatumumab, under the name Arzerra™, which purportedly aims to target CD20, a naturally occurring protein present on B-lymphocytes, which is believed to be involved in the mediation of lymphoproliferative and autoimmune diseases.

84. On information and belief, Arzerra™ is a form of the 2F2 monoclonal antibody produced in a recombinant murine cell line that is described in the World Intellectual Property Organization patent application publication number WO 2004/035607.

85. On October 26, 2009, the United States Food & Drug Administration issued License No. 1809 to GSK, authorizing GSK to market Arzerra™ with an indication for the treatment of chronic lymphocytic leukemia refractory to fludarabine and alemtuzumab, allowing Counter-Defendants to manufacture Arzerra™, market it in the United States, and introduce it into interstate commerce inside the United States. *See* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/125326s000ltr.pdf (last visited March 4, 2010).

86. Counter-Defendants are actively marketing Arzerra™ in the United States. For example, Counter-Defendants have made "prescribing information" available to the public. *See* http://us.gsk.com/products/assets/us_arzerra.pdf (last visited March 4, 2010).

87. On information and belief, Counter-Defendants have also begun importing Arzerra™ into the United States from the United Kingdom, where ofatumumab is manufactured by Lonza Biologics plc and where the final Arzerra™ product is manufactured, filled, labeled, and packaged by a GSK affiliate. *See* http://www.accessdata.fda.gov/drugsatfda_docs/ appletter/2009/125326s000ltr.pdf (last visited March 4, 2010).

88. On information and belief, Counter-Defendants have already sold or offered for sale Arzerra™ in the United States.

COUNT I
(Infringement Of The Cabilly II Patent)

89. Genentech and COH incorporate the allegations in Paragraphs 69-88 as if fully set forth herein.

90. By making, having made, marketing, preparing to sell, offering to sell, and selling Arzerra™ in the United States, importing Arzerra™ into the United States, and causing Lonza Biologics plc to manufacture ofatumumab intended for sale in and/or importation into the United States as the Arzerra™ product, Counter-Defendants have infringed and are infringing – directly, by contributory infringement, and/or by inducing the infringement of – one or more claims of the Cabilly II patent, literally and/or under the doctrine of equivalents.

91. Counter-Defendants' infringement has caused damage to Genentech and COH, and Genentech and COH are entitled to recover from Counter-Defendants the damages sustained by Genentech and COH as a result of Counter-Defendants' wrongful acts in an amount subject to proof at trial, but not less than a reasonable royalty.

92. Counter-Defendants' infringement has been, is, and will continue to be willful, justifying the award to Genentech and COH of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

93. Counter-Defendants' infringement has caused Genentech and COH to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Counter-Defendants' infringement is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Genentech and COH request that judgment be entered in favor of Genentech and COH and against Counter-Defendants:

1. Finding Counter-Defendants have infringed directly, have actively induced others to infringe, and have engaged in contributory infringement of the Cabilly II patent;

2. Finding Counter-Defendants will in the future infringe the Cabilly II patent;

3. Finding Counter-Defendants' infringement of the Cabilly II patent has been willful and deliberate;

4. Ordering Counter-Defendants to account for and pay to Genentech and COH all damages caused by the infringement of the Cabilly II patent;

5. Ordering Counter-Defendants to pay increased damages, up to treble damages, to Genentech and COH because of the willful nature of Counter-Defendants' infringement of the Cabilly II patent;

6. Ordering that this case be declared an exceptional case under 35 U.S.C. § 285 and that Genentech and COH be awarded their attorney's fees incurred in this action;

7. Ordering an award of Genentech and COH's costs and expenses for this action, pre- and post-judgment interest on any money damages award, and other charges to the maximum extent permitted;

8. Ordering a permanent injunction, prohibiting Counter-Defendants from infringing the Cabilly II patent; and

9. Ordering such other future relief as the Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Genentech and COH demand trial by jury of all issues so triable.

Dated: March 10, 2010

By: */s/ Daralyn J. Durie*
Daralyn J. Durie

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CERTIFICATE OF SERVICE

I certify that all counsel of record is being served on March 10, 2010 with a copy of this document via the Court's CM/ECF system.

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Dated: March 10, 2010

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